

*Amendment and Response to Office Action*  
*Serial No. 09/653,406*  
*Page 5*

### REMARKS

The present application is directed to methods for the treatment of a disorder or condition and for the controlled release of therapeutic or diagnostic agents by administering a biocompatible, polymerizable, macromer composition containing at least one NO carrying region or NO modulating compound. Prior to the present amendment, Claims 18 and 20-24 were pending. Applicants hereby amend Claims 18, 23 and 24 and add new dependent Claims 32-46. No new matter is introduced by the amendments. Reexamination and reconsideration of the application are requested in view of the claim amendments and following remarks.

#### *Support for New Dependent Claims*

Support for new dependent Claims 32-46 is found throughout the specification and the original claims. For example, Claim 32 is based on original Claim 5, Claim 33 is based on original Claim 11, Claims 34-40 are supported by Examples 1-9 on pages 19-22 of the specification, Claims 41-42 are supported on pages 22-25, Claims 43-43 are based on original Claims 4, 8 and 9, and Claim 46 is supported in the specification on p. 10, line 6, through p. 11, line 22, and on p. 23, lines 29-30.

#### *Claim Rejections under 35 U.S.C. §112*

##### Rejection of Claim 22 under 35 U.S.C. §112, first paragraph

The Examiner rejects Claim 22 under 35 U.S.C. §112, first paragraph. Claim 22 recites, in a Markush group, wound healing, restenosis, thrombosis, asthma, arthritis and erectile dysfunction. The Examiner asserts that the relationship of erectile dysfunction with asthma is not immediately discerned, and asks how arthritis is related to erectile dysfunction and asthma. Applicants have amended Claim 22 to recite that disorders or conditions in the Markush group are **affected by NO**. Support for the amendment is provided in the specification in combination with the knowledge of the person of ordinary skill in the art in

*Amendment and Response to Office Action*  
*Serial No. 09/653,406*  
*Page 6*

the field of NO signaling at the time when the application was filed. See p. 2, lines 1-21 of the specification, where it discusses how NO affects multiple biological responses through, for example, cGMP signaling pathway. The specification cites a number of relevant studies regarding NO signalling. Wound healing, restenosis, thrombosis, asthma, arthritis and erectile dysfunction are some of the response that were known to be affected by NO at the time of filing of the present application. Applicants respectfully submit that the amendment overcomes the rejection and request its withdrawal.

Rejection of Claim 23 under 35 U.S.C. §112, first paragraph

The Examiner rejects Claim 23 under 35 U.S.C. §112, first paragraph, as insufficiently enabled due to the language "to prevent surgical adhesions." Applicants have amended Claim 23 to clarify that the macromer reduces formation of surgical adhesions. Support for the amendment is found, for example, on p. 15, lines 30-31, of the specification. Applicants submit that the amendment overcomes the rejection and request its withdrawal.

Rejection of Claim 22 under 35 U.S.C. §112, second paragraph

The Examiner rejects Claim 22 under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner asserts that the conditions recited in the Markush group in Claim 22 appear unrelated. As discussed above, applicants have amended Claim 22 to recite that the disorders or conditions are affected by NO. The conditions recited in Claim 22 are related in that they are affected by NO signaling and, therefore, the claim is definite. Applicants submit that the amendment overcomes the rejection of Claim 22 and request its withdrawal.

Rejection of Claim 24 under 35 U.S.C. §112, second paragraph

The Examiner rejects Claim 24 under 35 U.S.C. §112, second paragraph, as indefinite. Applicants have amended Claim 24 to correct a typographical error. Applicants submit that the amendment overcomes the rejection of Claim 24 and request its withdrawal.

*Amendment and Response to Office Action*  
*Serial No. 09/653,406*  
*Page 7*

Rejection of Claim 18 under 35 U.S.C. §112, second paragraph

The Examiner rejects Claim 18 under 35 U.S.C. §112, second paragraph, as indefinite due to double recitation of the term "diagnostic agent." Applicants have amended Claim 18 to delete the second recitation of the term "diagnostic agent." Applicants submit that the amendment overcomes the rejection of Claim 24 and request its withdrawal.

*Non-Statutory Double Patenting Rejection*

The Examiner provisionally rejects Claims 20-24 of the present application under the judicially created doctrine of obviousness-type double patenting over Claims 20-25 of co-pending U.S. Patent Application No. 10/129,418, which is commonly owned with the present patent application. The co-pending application was filed on May 17, 2002, and has a later filing date than the present application. The obviousness-type double patenting rejection is the only rejection in U.S. Patent Application No. 10/129,418 (Notice of Allowance mailed). In accordance with the provisions of MPEP §1490, a terminal disclaimer was required by the Examiner in the later-filed application. Applicants assert that filing of the Terminal Disclaimer in the later-filed U.S. Patent Application No. 10/129,418 (enclosed herewith as Exhibit A) resolved any double-patenting issues that may arise when claims are allowed in the present application. In accordance with the provisions of MPEP §1490, applicants request withdrawal of the provisional non-statutory double patenting rejection in the present, earlier-filed patent application.

*Amendment and Response to Office Action*  
*Serial No. 09/653,406*  
*Page 8*

### CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed July 6, 2005. Applicants submit that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 815-6102 or to Jamie L. Greene at (404) 745-2473 is respectfully solicited.

The Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,



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Our Docket: 47400-0100 (47400-252658)

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## Patents

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Application of:**

Jennifer L. West et al.

**Serial No. 10/129,418**

Filed: May 17, 2002

## For: Nitric Oxide-Producing Hydrogel Materials

**Art Unit: 1615**

**Examiner: Azpuru, Carlos A.**

11/03/2005 TL0111 00000032 09653406

02 FC:2814

**65.00 OP**

**TERMINAL DISCLAIMER IN APPLICATION**

The owner, Rice University, of the entire interest in the above-identified present application hereby disclaims, except as provided below, the terminal part of any patent granted on the present application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending second Application No. 09/653,406, filed on September 1, 2000. The owner hereby agrees that any patent so granted on the present application shall be enforceable only for and during such period that said patent and any patent granted on the second application are commonly owned. This agreement runs with any patent granted on the present application and is binding upon the grantee of such patent, its successor or assigns.

In making the above disclaimer, the owner does not disclaim any terminal part of any patent granted on the present application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of any patent granted on the second application, as shortened by any terminal disclaimer filed prior to the patent grant, in the event that any such granted patent on the second application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner

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Terminal Disclaimer  
Serial No. 10/129,418  
Page 2

terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The fee required by 37 CFR § 1.20(d) accompanies this disclaimer.

The undersigned is an agent of record and is empowered to act on behalf of the owner.

Date: October 31, 2005

Elena S. Polovnikova

Name: Elena S. Polovnikova, Ph.D.

Our Docket: 47400-0101 (47400-272570)

Reg. No: 52,130